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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,963	12/30/2003	Alain Martin	CSI 1.0-007CIP	9919
<div>7590 Richard R. Muccino 758 Springfield Avenue Summit, NJ 07901</div>			<div>EXAMINER HUGHES, ALICIA R</div>	
			<div>ART UNIT 1614</div>	<div>PAPER NUMBER</div>
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/27/2006	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/747,963

Applicant(s)

MARTIN, ALAIN

Examiner

Alicia R. Hughes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 30-51 of the subject application are pending. Applicant's arguments and amendments filed on 03 July 2006 in response to the non-final rejection filed by this Office on 10 April 2006 have been fully considered, but they are not deemed to be persuasive. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied, and they constitute the complete set presently being applied to the instant application.

### **Rejections**

#### ***Nonstatutory Obviousness-Type Double-Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,689,810 [hereinafter referred to as "Martin '810"]. Claims 30-32 and 35-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,623,723 [hereinafter referred to as "Katz '723"]. Claims 30-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent Application No. 10/205,354 [hereinafter referred to as "Martin '354"]. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons maintained and reiterated from the previous Office Action entered on 10 April 2006.

Applicant argues that its invention claimed in the present application is patentably distinct from the inventions articulated in Martin '810, Katz '723, and Martin '354, because none of these cases recite the limitation "during ozone inhalation" in association with their inventions, like the present application does. The Applicant fails to factually analyze how the recitation of

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“during ozone inhalation” in its claims distinguishes them and thereby, makes its invention distinct. Moreover, the Applicant has failed to provide any facts to support the assertion that lack of the phraseology “during ozone inhalation” in Martin ‘810, Katz ‘723, and Martin’354 means, in fact, that ozone is not inhaled. To the contrary, it is known by those of skill in the art that ozone is present in the atmosphere and as a result, inhaled on some level at all times. See Concise Encyclopedia of Chemistry, p.770, col.2).

As argumentation lacking factual support is non-persuasive, generally, and the Applicant has not provided justification substantiated by fact as to why addition of the phraseology “during ozone inhalation” in its claim makes its invention patentably distinct from Martin ‘810, Katz ‘723, and Martin’354, all nonstatutory obviousness-type double patenting rejections made in the Office Action filed on 10 April 2006 and reiterated, *infra*, are maintained.

***Claim Rejections – 35 U.S.C. §102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless–

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30-32, 35, and 43-51 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of WO/97/10818 [hereinafter referred to as “Katz ‘818”], U.S. Patent No. 5,798, 388 [hereinafter referred to as “Katz ‘388”], U.S. Patent No. 5,939,459 [hereinafter referred to as “Katz ‘459”], and U.S. Patent No. 5,952,384 [hereinafter referred to as “Katz ‘384”][collectively referred to herein as “Katz”].

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The rejections germane to this portion of the present Office Action as set forth in the Office Action mailed on 10 April 2006 are incorporated herein by reference.

In further expounding on the analysis in this Office's previous rejection, the nitric oxide mediator in the instant application comes within the purview of an "inflammatory mediator" noted in Katz. Moreover, Katz defines pyruvates and pyruvate precursors as inflammatory mediators while the present invention defines pyruvates and pyruvate precursors as nitric oxide mediators. While the terminology may differ slightly, the functionality of both the nitric oxide mediators in the instant application and the inflammatory mediators in Katz are identical. Simply stated, a pyruvate is a pyruvate is pyruvate, and similarly, a pyruvate precursor is a pyruvate precursor. It is a pyruvate precursor. An alteration in the label of either has no impact on their chemical and physiological properties and effects.

As is well known by those of ordinary skill in the art, nitric oxide effectively kills microorganisms, but is ineffective when impacted adversely by the presence of oxygen radicals. An over-saturation of microorganisms creates infection and disease, which in turn, can cause inflammation. Pyruvates and pyruvate precursors, acting as inflammatory mediators and nitric oxide mediators, prevent the deactivation of nitric oxide otherwise caused by the presence of oxygen radicals, thereby enabling a stabilized form of nitric oxide, which effectively kills microorganisms and thereby treats illnesses and diseases caused thereby.

Agreeably, anticipation does require that prior art forming the basis for a 35 U.S.C. §102(b) rejection contain art in a single reference that meets each and every functional limitation set forth in an Applicant's claim. Katz collectively, and Katz '388, Katz '459, and Katz '818, individually meet the limitations set forth in claims 30-32, 35, and 43-51.

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***Claim Rejections – 35 U.S.C. §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30 and 33-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over W/O 02/074301 [hereinafter referred to as "Fink et al."] in view of U.S. Patent Application No. 5,192,528 [hereinafter referred to as "Radhakrishnan et al."].

The rejections germane to this portion of the present Office Action as set forth in the Office Action mailed on 10 April 2006 are incorporated herein by reference.

Applicant argues that although Fink et. al. do disclose a composition that may include  $\alpha$ -ketoalkanoic acid, physiologically-acceptable salts, esters, and amides thereof, the examples provided therein are limited to the use of ethyl pyruvate. Then, Applicant proceeds to engage a discussion on how the use of ethyl pyruvate differs from the pyruvates taught in the current application.

The discussion on why ethyl pyruvate was not a pyruvate contemplated in the current application is improper for two reasons. First, the claim drawn to pyruvates in the current application was not rejected under this section of the Office Action as being obvious over Fink et al. in view of Radhakrishnan. And second, even if the pyruvates were within the purview of rejections made in this section pursuant to 35 U.S.C. §103(a), the discussion would potentially be unfounded still, since the enablement or teaching of a subject matter, depending on the subject

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matter, of course, does not have to be illustrated by example in a specification to be included as part of the claimed invention.

With regard to  $\alpha$ -ketoalkanoic acid, physiologically-acceptable salts, esters, and amides thereof, by Applicant's own admission, Fink et al. do teach a method of administering a composition containing these compounds (Applicant's Response to Non-Final Rejection, p. 17, lines 17-20).

### *Conclusion*

No claims are allowed.

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

20 November 2006

ARH

*Ardin H. Marschel* 12/22/06  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER